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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,414	03/31/2004	Arnold C. Takemoto	ATAKEM-004-USA	7749

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EXAMINER	
COE, SUSAN D	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/815,414	TAKEMOTO, ARNOLD C.	
	Examiner	Art Unit	
	Susan D. Coe	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claim 1 is currently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claim 1 is indefinite because the Markush language used in ingredients a) - e) is very confusing. The Markush language is not in accordance with standard Markush language and makes it unclear what the actual members of the Markush group are. The unclear language coupled with the use of "e.g." makes it unclear what ingredients are actually required in the composition.

3. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required

feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 (a) recites the broad recitation "plant indoles", and the claim also recites "e.g. as diindolemethane" which is the narrower statement of the range/limitation.

In addition, claim 1 (b) recites the broad recitation of "plant flavonoids, polyphenols, and related substances," and the claim also recites "e.g. resveratrol and piceatannol" which is the narrower statement of the range/limitation.

Claim 1 (c) recites the broad recitation of "D-glucaric acid and derivatives thereof," and the claim also recites "e.g. calcium D-glucarate and 1,4-GL" which is the narrower statement of the range/limitation.

Claim 1 (e) recites the broad recitation of "phospholipids" and "sources thereof" and the claim also recites "e.g. phosphatidyl choline" and "e.g. lecithin" which is the narrower statement of the range/limitation.

4. Claim 1 (a) is indefinite because applicant has not fully described all possible sources of the plant indoles; thus, the metes and bounds of the claim are unclear.

5. Claim 1 (b) is indefinite because it is unclear what substances applicant considers to be "related substances" to the plant flavonoids, polyphenols, and stilbenes. In addition, the metes and bounds of the claim are unclear because applicant has not fully described all possible sources of the flavonoids, polyphenols, or stilbenes.

6. Claim 1 (c) is indefinite because applicant has not fully described what substances are considered to be "derivatives" of D-glucaric acid. Many possible substances could be "derived"

from D-glucaric acid including simple substances like carbon. In addition, the metes and bounds of the claim are unclear because applicant has not fully described all possible sources of the D-glucaric acid.

7. Claim 1 (d) is indefinite because the metes and bounds of the claim are unclear because applicant has not fully described all possible sources of the medium chain triglyceride. Please note that applicant defines "medium length triglycerides" as fatty acids with six to 12 carbon atoms (see page 34 of the spec).

8. Claim 1 (e) is indefinite because the metes and bounds of the claim are unclear because applicant has not fully described all possible sources of the phospholipids.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,503,506 and US Pat. Pub. No. 2002/0098253.

Applicant's claim is directed towards a composition comprising a plant indole or a source of a plant indole. Diidolemethane is given as an example of the indole. The composition also contains a plant flavonoid, polyphenol, or stilbene or a source of these substances. Resveratrol and piceatannol are given as examples. The composition also contains a D-glucaric acid, with calcium D-glucarate as a specific example. The composition also contains a medium chain

triglyceride (defined by applicant in the specification as having six to 12 carbon fatty acid chain). The composition also contains phospholipids or a source thereof, with phosphatidyl choline and lecithin as examples.

US '506 teaches an antioxidant composition. The composition contains medium chain triglycerides, fruit polyphenols and lecithin (see top of column 9 and claims).

US '253 teaches an antioxidant composition that contains broccoli, citrus fruit bioflavonoids, bilberry extract, calcium D-glucarate, and grape seed extract (see page 5, first column). According to applicant's specification, broccoli, grapes, and berries are sources of plant indoles (see page 33). In addition, applicant's specification states that grape seed extract is a source of polyphenols (see page 33).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in antioxidant compositions. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in antioxidant compositions, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating antioxidant compositions. Therefore, the artisan would have been motivated to combine the claimed ingredients into a

single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

10. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,300,377 and US Pat. Pub. No. 2002/0098253.

US '377 teaches a composition that treats heart problems (see column 1). The composition contains medium chain triglycerides, phosphatidylcholine, lecithin, grape seed, resveratrol, and bilberry extract (see claims 10, 11, 13, and 14).

US '253 teaches an antioxidant composition that contains broccoli, citrus fruit bioflavonoids, bilberry extract, calcium D-glucarate, and grape seed extract. The composition is used to maintain heart health (see page 5, first column). According to applicant's specification, broccoli, grapes, and berries are sources of plant indoles (see page 33). In addition, applicant's specification states that grape seed extract is a source of polyphenols (see page 33).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions for heart health. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in compositions for heart health, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions for heart health. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 11/019,491.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims comprise the same ingredients, diindolemethane, grape skin extract (source of polyphenols), calcium D-glucarate, medium chain triglycerides, and phospholipids.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/816,769. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims comprise the same ingredients, diindolemethane, grape skin extract (source of polyphenols), calcium D-glucarate, medium chain triglycerides, and phospholipids.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 9:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access

to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.

Susan D. Coe
11-8-05

Susan D. Coe
Primary Examiner
Art Unit 1655